K040456

3/9/04

GRIFOLS	TECHNICAL EVALUATION DOCUMENTATION	# Document: TED-FLEBOSET MULTIPLE-01

SECTION 1 – FLEBOSET MULTIPLE: 510(k) SUMMARY

DATE OF SUBMISSION: 2004-02-06

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Technical Director

DEVICE TRADE NAME: FLEBOSET MULTIPLE
COMMON NAME: I.V. FLUID TRANSFER SETS
FLUID DELIVERY TUBING

CLASSIFICATION NAME: SET, I.V. FLUID TRANSFER (21 CFR 880.5440, LHI)
TUBING. FLUID DELIVERY (21 CFR 880.5440, FPK)

PREDICATE DEVICE: Automix 3+3 Compounder Transfer Set (BAXTER HEALTHCARE CORP.)
Medrad Transfer Set (MEDRAD INC.)
Merit Medical Contrast Management System (MERIT MEDICAL SYSTEMS, INC.)

DEVICE DESCRIPTION: FLEBOSET MULTIPLE is a fluid transfer tubing set used to enable continuous (uninterrupted) delivery of drug solutions from 6 glass source containers. It is used in pharmacy compounding or for I.V. fluid transfer to minimize tubing manipulation when working with small volume source containers. The device is made up of 6 spikes connected in series with flexible tubing segments, each segment with an individual clamp. The set terminal, for connection to the pharmacy compounding device sets or administration sets (gravity or pump) consists of a spikeable twist-off valve connector.

49

SECTION 1 – FLEBOSET MULTIPLE: 510(k) SUMMARY

INTENDED USE:

FLEBOSET MULTIPLE is an ancillary device used as fluid pathway through which substances from 6 glass source flasks containing the same solution may be continuously delivered for:
(a) Pharmacy compounding, when used in conjunction with the GRI-FILL 2.0 pharmacy compounding device and associated transfer sets, and
(b) I.V. administration, when used in conjunction with a gravity or pump infusion set to channel the solution from the source containers to the infusion set.
The device should not be used with lipids.

SUMMARY OF COMPARISON WITH PREDICATE DEVICE:

In the establishment of substantial equivalence, FLEBOSET MULTIPLE is compared with other fluid delivery tubing used in pharmacy compounding and I.V. administration. The following table summarizes the similarities of the principal technological characteristics and features of both predicate and new devices.

#	Characteristic / Feature	FLEBOSET MULTIPLE	PREDICATES		
			BAXTER Automix 3+3 (transfer set presented together with compounder) K894827	MEDRAD Transfer Set K022431	MERIT MEDICAL Transfer Sets K961794
1.	Intended use / Claims	FLEBOSET MULTIPLE is an ancillary device used as fluid pathway through which substances from 6 glass source flasks containing the same solution may be continuously delivered for: (a) Pharmacy compounding, when used in conjunction with the GRI-FILL 2.0 pharmacy compounding device and associated transfer sets, and (b) I.V. administration, when used in conjunction with a gravity or pump infusion set to channel the solution from the source containers to the infusion	Positive displacement fluid compounding system employing the 3+3 compounder, TRANSFER SETS, empty Viaflex or Travamulsion containers with connectors and multitask computer software to provide compounding of a wide variety of fluids	The Medrad Transfer Set is medical disposable device used to transfer intravascular contrast media and saline from a spikeable container to a power injector syringe. The device components consist of a vented spike, connector tube, a means of manually stopping flow, female luer, and individually packaged sterile caps.	Contrast media delivery systems used to transfer I.V. contrast media from a spikeable container to a syringe.

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#	Characteristic / Feature	FLEBOSET MULTIPLE	PREDICATES		
			BAXTER Automix 3+3 (transfer set presented together with compounder) K894827	MEDRAD Transfer Set K022431	MERIT MEDICAL Transfer Sets K961794
		set. The device should not be used with lipids.			
2.	Technological features: -Sterilization -Contact with patient -Source solutions	Ethylene Oxide NO – Intended for use with the pharmacy compounding device or INDIRECT - May be used on-line with patient, upstream of the gravity or pump administration sets. 6	Radiation NO - Intended for use with the pharmacy compounding device. 3 or 6.	Ethylene Oxide NO – Must be removed from the syringe before the syringe can be connected to the patient. 2	Ethylene Oxide INDIRECT - May be used on-line with the patient through a syringe with stopcock or a manifold port. 1
3.	Principle Materials	PVC with DEHP plasticizer	PVC with DEHP plasticizer	PVC	Flexible plastic
4.	Sterility	Sterile	Sterile	Sterile	Sterile

From the above table, it can be established that the new device and the predicate devices are very similar.

SUMMARY DISCUSSION OF NON-CLINICAL DATA:
All materials used in the construction of FLEBOSET MULTIPLE have been subject to chemical and biological testing in accordance with the applicable requirements taking account of its intended use.

Functional laboratory testing performed in foreseeable operating conditions showed correct operation of the device as per its intended use.

CONCLUSIONS:
We believe the intended use, the indications for use, the functionality and the operation of FLEBOSET MULTIPLE and the predicate devices for fluid transfer both in pharmacy compounding and for I.V. administration are essentially the same. Hence, substantial equivalence of FLEBOSET MULTIPLE with the legally marketed devices may be established.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 9 2004

Laboratorios Grifols, S.A.
C/O Ms. Susan Gill
Responsible Third Party Official
Underwriters Laboratories, Incorporated
12 Laboratory Drive
P.O. Box 13995
Research Triangle Park, North Carolina 27709-3995

Re: K040456
Trade/Device Name: Fleboset Multiple
Regulation Number: 880.5440
Regulation Name: Set, Intravenous Fluid Transfer
Regulatory Class: II
Product Code: LHI
Dated: February 20, 2004
Received: February 23, 2004

Dear Ms. Gill:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

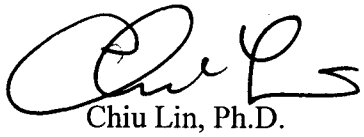
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PREMARKET NOTIFICATION
INDICATIONS FOR USE STATEMENT
(as required by ODE for all 510(k) received after Jan. 1, 1996)

510(k) Number: K040456

Device Name: FLEBOSET MULTIPLE

Indications for Use:

FLEBOSET MULTIPLE is an ancillary device used as fluid pathway through which substances from 6 glass source flasks containing the same solution may be continuously delivered for:

(a) Pharmacy compounding, when used in conjunction with the GRI-FILL 2.0 pharmacy compounding device and associated transfer sets, and
(b) I.V. administration, when used in conjunction with a gravity or pump infusion set to channel the solution from the source containers to the infusion set.

The device should not be used with lipids.
This device is intended to be used by trained health-care personnel. It is restricted to sale by or on order of a physician.

(Do not write below this line. Continue on another page in needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Steve Nawaz, Interim Branch Chief
(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K040456

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter Use ___